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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,320	06/15/2001	Andrew Carver	5490-000216	8429
27572	7590	10/29/2004	EXAMINER	
HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			PHILOGENE, PEDRO	
			ART UNIT	PAPER NUMBER
			3732	
DATE MAILED: 10/29/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/882,320

Applicant(s)

CARVER ET AL.

Examiner

Pedro Philogene

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/23/04 has been entered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-14 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 1, lines 5-7, applicant positively recites part of a human, i.e. "a first end portion inter-connectable with a first phalange a second portion inter-connectable with a second phalange". Thus claims 1- 14 include a human part within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. In re Wakefield, 422 R 2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3732

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,12,14,29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (4,516,569) in view of Berman (6,017,366).

With respect to claims 1, 29, Evans et al disclose a device (20) for insertion into a first phalange and a second adjacent phalange, as set forth in column 1, lines 13,14 and column 3, lines 17-19, so as to fuse, as set forth in column 3, lines 7-11, the first phalange to the second phalange, comprising, a substantially elongated member (21); wherein the member (21) has a first end portion capable of being inter-connectable with the first phalange, a middle portion and a second end portion capable of being inter-connectable with the second phalange; as best seen in FIG.5, spaced and opposed from the first end portion, wherein the middle portion has a curvature such that a fixed angle, as best seen in FIG.5, is formed between the first end portion and the second portion. Curvature has been interpreted to mean that the first and second end portions are at an angle as shown in FIG.5 of Evans and FIG.4 of the instant application. This is consistent with applicant's lack of disclosure of any radius of curvature.

It is noted that Evans did not teach the use of a resorbable material, as claimed by applicant. However, in a similar art, Berman evidences the use of a resorbable material in devices, which are to be inserted into bones so that the implant is conformable due to its inherent compliance and this conformability allows the implant to accommodate to a substantial extent the variable bone shapes. As to the middle portion operable to have a user formable curvature, the resorbable material of Berman would

allow a user to fix the angle in the device of Evans et al., as set forth in column 5, lines 20-42, column 7, lines 1-5 and the abstract.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Evans et al. to be made of resorbable material as taught by Berman so that the implant is conformable due to its inherent compliance and this conformability allows the implant to accommodate to a substantial extent the variable bone shapes.

The claimed phrase "the middle portion comprises a user formable curvature" is being treated as a product-by-process limitation, that is that the implant angle is made by the user. As set forth in MPEP 2113, product-by process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps.

With respect to claims 12,14, the above combination of references teaches all the limitations; as set forth in the abstract of Berman would allow a user to fix the angle in the device of Evans et al., as set forth in column 5, lines 20-42, column 7, lines 1-5 and the abstract.

Claims 2-11,13,15-28,30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (4,516,569) in view of Berman (6,017,366) in view of Bramlet (5,984,970).

With respect to claims 2-11,13,15-25,30, it is noted that the above combination of references teaches all the limitations, except for a the first end portion and the second end portion having a surface portion for facilitating retention within the first phalange and the second phalange; as claimed by applicant. However, in a similar art, Bramlet

evidences the use of a device having a first end portion and a second end portion having a surface portion for facilitating retention within the first phalange and the second phalange such that a substantive holding force will be developed when the end portion is threadably secured within the bone of the phalange.

Therefore, given the teaching of Bramlet, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the fins of the device of Evans/Berman with the threads of the device of Bramlet to be implanted in the phalanges of a finger such that a substantive holding force will be developed when the end portions are threadably secured within the bone of the phalanges.

As to the angle of 172 degrees in claims 15 and 30; it would have been obvious to one having ordinary skill in the art at the time the invention was made to reach the optimum angle, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claims 26-28,31,32 the method steps, as set forth, would have been obviously carried out in the operation of the device, as set forth above.

Response to Amendment

Applicant's arguments with respect to claims 1-30,32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

6,332,779

12-2001


Boyce et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pedro Philogene
October 28, 2004


PEDRO PHILOGENE
PRIMARY EXAMINER